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K032432
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510 (k) Summary

Date Prepared [21 CFR 807.92(a)(1)]

August 5, 2003

Submitter's Information [21 CFR 807.92(a)(1)]

Joseph M. Azary
C/o Busse Hospital Disposables, Inc.
P.O. Box 2156
Huntington, CT 06484

Azary Technologies has received authorization to submit this 510(k) on behalf of the sponsor Busse Hospital Disposables, Inc, 75 Arkay Drive, Hauppauge, NY 11788. Busse Hospital Disposables, Inc. is an FDA-registered medical device under establishment# 2433012.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade names are: Busse Hospital Disposables Spinal Manometer

Common Name: Spinal Fluid Manometer

Classification: Class II, 80 FMJ, 21 CFR 880.2500

Predicate Device [21 CFR 807.92(a)(3)]

The spinal manometer is substantially equivalent to several other devices on the market including: Allegiance Spinal Manometer, B. Braun Spinal Manometer, and SIMS Spinal Manometer.

Description of the Device [21 CFR 807.92(a)(4)]

The Spinal Manometer is used as part of a lumbar puncture procedure in which cerebrospinal fluid is extracted for examination, and pressure of the spinal fluid is measured. The cerebrospinal fluid is generally used to diagnose if there are problems with the central nervous system or spinal cord.

The procedure requires insertion of a spinal needle into the lumbar section of the spine. The spinal manometer is attached to the hub of the needle with a three-way stopcock. An extension tube may be used to reduce movement of the spinal needle and patient discomfort. The extension tube attaches to the spinal needle hub and the stopcock.

The Cerebrospinal Fluid (CSF) pressure is measured while the needle is connected to the Spinal Manometer directly or through an extension tube. The normal range for CSF pressure is 80mm-180mm (8cm-18cm) H2O. CSF pressure over 200mm (20cm) H2O is considered high and pressure less than 80mm (8cm) H2O is low.

The Spinal Manometer does not directly contact the patient nor does it contact body fluids intended to be re-introduced into the human body. The Spinal Manometer is composed of polyethylene and the luer lock and connector is composed of polycarbonate.

The Spinal Manometer is a two-piece Spinal Manometer. The additional Spinal Manometer length is available if required. The two-pieces are connected using a polycarbonate connector.

The Spinal Manometer is packaged as part of a convenience kit for lumbar puncture. The Spinal Manometer is placed in a rigid tray composed of high impact plastic (poly styrene). The tray is wrapped and packaged in a soft pouch with Tyvek lid. The pouch is heat-sealed.

The convenience kit includes a variety of devices used in the lumbar puncture procedure including 20 gauge spinal needle with stylet, syringe with needle, 22 gauge needle, spinal manometer, 5" extension tube, three-way stopcock, three sponge sticks, three gauze pads, four vials with screw caps, fenestrated drape, towel, Lidocaine Hydrochloride, CSR wrap, and bandage. The other devices in the convenience kit are either exempt from 510(k) or are purchased from other manufacturers who have obtained 510(k) clearance on the devices. Busse certifies that the devices in the kit are either legally marketed preamendment devices, are exempt from premarket notification, or have been found to be substantially equivalent through the premarket notification process for the use for which the kit is to be intended.

The subject devices are composed of the following materials:

Component	Material	Details
Manometer	Polyethylene	No patient contact
Luer Lock	Polycarbonate	No patient contact
Connector	Polycarbonate	No patient contact

Intended Use [21 CFR 807.92(a)(5)]

The device is intended to measure the pressure of the Cerebrospinal Fluid (CSF) during a lumbar puncture procedure.

Technological Characteristics [21 CFR 807.92(a)(6)]

Busse Hospital Disposables, Inc. believes that the subject device is substantially equivalent to the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

A qualified third party calibration laboratory tested the accuracy of the device. MCS Calibration Inc. of Hollbrook, NY is certified to ISO 17025 and ISO 9002. The Spinal Manometer was found to meet the required accuracy of +/- 2mm (+/- 0.2cm).

Busse Hospital Disposables, Inc. believes that the subject device is substantially equivalent to other devices that have previously received FDA 510(k) clearance including the predicate device.

Conclusion [21 CFR 807.92(b)(3)]

We believe the differences between the subject device and predicate device are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2003

Joseph M. Azary
Azary Technologies, LLC
P.O. Box 2156
Huntington, Connecticut 06484

Re: K032432
Trade Name: Busse Hospital Disposables, Inc. Spinal Manometer
Regulation Number: 880.2500
Regulation Name: Spinal Fluid Manometer
Regulatory Class: II
Product Code: 80 FMJ
Dated: August 5, 2003
Received: August 6, 2003

Dear Mr. Azary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Lidocaine Hydrochloride USP, 1%, 2mL, which are subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market. If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (301) 594-4692. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

5 10(k) Number (if known): _____

Device Name: Busse Hospital Disposables. Inc. Spinal Manometer

The device is intended to measure the pressure of the Cerebrospinal Fluid (CSF) during a lumbar puncture procedure.

Patricia Cucuzzella

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032432

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)